510(K) SUMMARY

FEB 18 2010

SUBMITTER:

r4 Vascular, Inc.
7550 Meridian Circle
Suite 150
Maple Grove, Minnesota 55369

ESTABLISHMENT REGISTRATION NUMBER:

3006242715

CONTACT:

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DATE PREPARED:

May 20, 2009

NAME OF MEDICAL DEVICE:

Proprietary Name:	Duraspan™ Long-Term Hemodialysis Catheter
Common/Usual Name:	Long Term Hemodialysis Catheter
Classification Name:	78 MSD - Catheter, Hemodialysis, Implanted

DEVICE CLASSIFICATION:

Classification Panel:	Gastroenterology and Urology
Regulatory Class:	III
Product Code:	MSD
Regulation Number:	21 CFR 876.5540

PREDICATE DEVICES:

Proprietary Name:	Duraspan™ Long-Term Hemodialysis Catheter (Ultra)
Common/Usual Name:	Long-Term Hemodialysis Cathter
Classification Name:	78 MSD - Catheter, Hemodialysis, Implanted

DEVICE DESCRIPTION:

The Duraspan™ Dialysis Catheter is designed for patients with End Stage Renal Disease needing chronic hemodialysis. The catheter is inserted percutaneously through the Subclavian or Jugular veins and placed in the venous system of the patient. Once in place, the catheters two proximal luer connectors are connected to a hemodialysis machine's blood lines. The machine's pump draws blood through the proximal lumen, indicated with the red connector, removing blood from the patient. The blood is processed in the hemodialysis filter or apheresis centrifuge. The blood is then returned through the lumen, marked by a blue connector, exiting out the most distal tip. The tip of the catheter is staggered to reduce recirculation of the blood.

The catheters include female luer locking adapters and a tissue ingrowth cuff for fixing the catheters in a subcutaneous tunnel. The Duraspan™ kit includes a catheter and introduction components. The catheter is supplied sterile.

The Duraspan™ product line has catheters in a 15.5 Fr dual lumen. The catheters come in a variety of lengths (24-55cm) for patient specificity and access preference.

The Duraspan™ is similar to the Duraspan™ Ultra with a reduced tip stagger to address the variability of the dimensions of the vena cava in patients allowing for appropriate positioning of the arterial and venous lumens within the vena cava and right atrium.

INTENDED USE/INDICATION FOR USE:

The r4 Duraspan™ long-term dialysis catheter is indicated for attaining short and long term (>30 days) vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein or femoral vein. Catheters 40 cm and longer are for femoral vein insertion. The ability of the Biomimetic Coating to reduce platelet adhesion and thrombus accumulation is supported exclusively by in-vitro and animal testing.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

Technologically the Duraspan™ is identical to the r4 Duraspan Ultra in terms of design and performance. The only difference is a reduced tip stagger. The Duraspan™ was thoroughly tested with tests based on existing standards and test methods and demonstrates that the Duraspan™ is substantially equivalent to the listed predicates.

There are no new questions raised regarding safety or efficacy of the Duraspan™ catheter.

CONCLUSIONS

Based on indications for use, technological characteristics and performance testing the Duraspan™ catheters met the requirements for its intended use and the Duraspan™ is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available catheters/cited predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Laurie Lewandowski
Director, Quality and Regulatory Affairs
r4 Vascular, Inc.
7550 Meridian Circle
Suite 150
MAPLE GROVE MN 55369

FEB 18 2010

Re: K100169
Trade/Device Name: Duraspan™ Long-Term Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: January 18, 2010
Received: January 20, 2010

Dear Ms. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Janine M. Morris, Director (Acting)
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100169

Device Name: Duraspan™ Long-Term Hemodialysis Catheter

Indications for Use:

The r4 Duraspan™ and the Duraspan™ Ultra long-term dialysis catheter is indicated for attaining short and long term (>30 days) vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, external jugular vein, subclavian vein or femoral vein. Catheters 40 cm and longer are for femoral vein insertion. The ability of the Biomimetic Coating to reduce platelet adhesion and thrombus accumulation is supported exclusively by in-vitro and animal testing.

Prescription Use: X AND/OR Over-the-Counter Use: _____
Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K100169